

Attorney Docket No.: **270/070 (UMD-0070)**  
Inventors: **Langenfeld, John**  
Serial No.: **10/044,716**  
Filing Date: **January 11, 2002**  
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**REMARKS**

Claims 1-64 are pending in this application. Claims 1-64 have been subjected to a Restriction Requirement under 35 U.S.C. §121. Claim 12 has been amended. Claims 5, 7, 8, 10, 13, 26, 28 and 30 have been canceled. No new matter has been added by these amendments. Applicant is respectfully requesting reconsideration of the restriction requirement in view of the following remarks.

The Examiner suggests that restriction of the present invention into the following groups is required:

Group I, claims 2 and 5-10, drawn to a method for treatment of cancer comprising administering to a patient a therapeutically effective amount of a polypeptide that binds specifically to bone morphogenetic protein-2 (BMP-2);

Group II, claims 3 and 4, drawn to a method for treatment of cancer comprising administering to a patient a therapeutically effective amount of a polypeptide that binds specifically to a receptor of BMP-2;

Group III, claim 11, drawn to a method for treatment of cancer comprising administering to a patient a therapeutically effective amount of an antibody that binds BMP-2;

Group IV, claim 12, 13, and 37-45, drawn to a method for treatment of cancer comprising administering to a patient a therapeutically effective amount of an antisense oligonucleotide or an expression vector encoding an antisense oligonucleotide, wherein said oligonucleotide binds a BMP-2 encoding nucleic acid sequence;

Group V, claims 23 and 26-30, drawn to a method for treatment of cancer comprising administering to a patient a therapeutically effective amount of an expression vector encoding

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an inhibitor of an activity of BMP-2, wherein said inhibitor is a polypeptide that binds BMP-2;

Group VI, claims 24 and 25, drawn to a method for treatment of cancer comprising administering to a patient a therapeutically effective amount of an expression vector encoding an inhibitor of an activity of BMP-2, wherein said inhibitor is a polypeptide that binds a receptor of BMP-2;

Group VII, claims 46-49, drawn to an article of manufacture comprising a polypeptide that binds specifically to BMP-2, which cannot be classified, since the chemical and biological nature of the BMP-2 activity inhibitor has not been specified; and

Group VIII, claims 50-64, drawn to a method for the diagnosis of cancer in a patient comprising measuring the level of BMP-2 in the patient;

The Examiner suggests that claims 1, 14-22 and 31-36 are linking claims. Specifically, claims 1 and 14-19 are considered to link claims drawn to a method for treatment of cancer comprising administering a BMP-2 activity inhibitor, wherein said inhibitor is selected from the group consisting of (a) a polypeptide that binds specifically to BMP-2, (b) a polypeptide that binds specifically to a receptor of BMP-2, (c) an antibody to BMP-2, and (d) an antisense oligonucleotide that binds at least a portion of a BMP-2 nucleic acid sequence.

Further, claims 20-22 and 31-36 are considered to link claims drawn to a method for treatment of cancer comprising administering an expression vector encoding a BMP-2 activity inhibitor, wherein said inhibitor is selected from the group consisting of (a) a polypeptide that binds specifically to BMP-2, (b) a polypeptide that binds specifically to a receptor of BMP-2,

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and (d) an antisense oligonucleotide that binds at least a portion of a BMP-2 nucleic acid sequence.

It is suggested that the restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). The Examiner acknowledges that upon allowance of the linking claim(s), the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claims(s) will be entitled to examination in the instant application.

The Examiner suggests that the inventions listed as Groups I-VI and VIII are independent and distinct from each other. Specifically, Groups I and II have been suggested as being distinct products since the invention of Group I comprises administering a protein that binds to BMP-2 and the invention of Group II comprises administering a protein that binds to a receptor of BMP-2 to inhibit the activity of BMP-2. Likewise, it is suggested that the inventions of Groups II and III are distinct since the invention of Group II comprises administering a polypeptide and the invention of Group III comprises administering an antibody. Similarly, the Examiner suggests that the inventions of Groups I and III are distinct since the invention of Group I comprises administering a polypeptide and the invention of Group III comprises administering an antibody. The Examiner further suggests that Groups IV-VI are distinct from any of the inventions of Groups I-III because the inventions of groups IV-VI comprise administering polynucleotides which are chemically distinct from and do not encode any of the administered polypeptides or antibodies of Groups I-III. Group

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VIII has been suggested as being distinct from any one of the inventions of Groups I-VI because the claimed methods of treatment of cancer (Groups I-VI) and the claimed method for diagnosis of cancer (Group VIII) are unrelated because they are materially different and have different modes of operation.

The Examiner acknowledges that inventions of Group VII and any of the inventions of Groups I-IV are related as product and process of use; however, because the article of manufacture comprising a BMP-2 activity inhibitor can be used in a materially different process, it is suggested that these inventions are distinct. The Examiner has indicated that upon election and allowance of product claims, withdrawn process claims will be rejoined in accordance with the provisions of MPEP §821.04. Applicant is required to elect one of the Groups to be examined.

To the extent that the claims of Groups I and V are drawn to patentably distinct species of the invention (*i.e.*, a polypeptide that binds BMP-2 selected from the group consisting of human noggin (SEQ ID NO:4), mouse noggin (SEQ ID NO:6), chordin, Cerberus 1 homolog, and gremlin), the Examiners requires that Applicant elects one polypeptide to be examined.

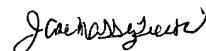
The present invention relates to methods for treating cancer by inhibiting BMP-2 activity and methods for diagnosing cancer based on the presence of BMP-2. Upon review of the restriction requirement and pending claims, Applicant has appreciated the necessity of clarifying the instant invention to facilitate the search for the relevant prior art pertaining to BMP-2 and its association with cancer. Accordingly, Applicant has canceled claims 5, 7, 8, 10, 13, 26, 28, and 30.

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Further, Applicant respectfully disagrees with the Examiner's suggestion that an antibody is not considered a polypeptide because it is composed of four polypeptides. As taught at paragraph 0042 of the instant specification, an antibody refers to "polyclonal and monoclonal antibodies, chimeric, single chain, and humanized antibodies..." and is not restricted to four polypeptide chains. Therefore, in accordance with the teachings of the instant invention, an antibody is a polypeptide and, therefore it is respectfully requested that the restriction of claims 2 and 5-11 into Groups I and III be reconsidered and withdrawal.

However, in an earnest effort to be completely responsive, Applicant hereby elects to prosecute Group I, claims 2 and 5-10, drawn to a method for treatment of cancer comprising administering to a patient a therapeutically effective amount of a polypeptide that binds specifically to bone morphogenetic protein-2 (BMP-2), classified in class 514, subclass 2, with traverse.

Respectfully submitted,



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